IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

EAGLE PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No.
	)	
SLAYBACK PHARMA LLC,	)	
	)	
Defendant.	)	

COMPLAINT

Plaintiff Eagle Pharmaceuticals, Inc. ("Eagle"), by its attorneys, for its Complaint, alleges as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202, that arises out of the submission of New Drug Application ("NDA") No. 212209 by Slayback Pharma LLC ("Slayback" or "Defendant") to the United States Food and Drug Administration ("FDA") seeking approval to manufacture and sell its proposed product which Slayback asserts to be bioequivalent to Eagle's BALRAPZO®, 100 mg/4 mL (25 mg/mL) Bendamustine Hydrochloride Injection product prior to the expiration of Eagle's U.S. Patent Nos. 9,265,831 ("the '831 patent"); 9,572,796 ("the '796 patent"); 9,572,797 ("the '797 patent"); and 10,010,533 ("the '533 patent") (collectively, "the Patents-in-Suit").

PARTIES

2. Plaintiff Eagle Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, with its corporate offices and principal place of business at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677.

3. On information and belief, Defendant Slayback Pharma LLC is a corporation organized and existing under the laws of Delaware, with its principal place of business at 301 Carnegie Center, #303, Princeton, New Jersey 08550.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

5. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b) at least because Slayback is organized and existing under the laws of Delaware and therefore resides there for purposes of venue.

6. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Slayback.

7. This Court has personal jurisdiction over Slayback because, upon information and belief, Slayback is a corporation organized and existing under the laws of Delaware and maintains a registered agent for service of process in Delaware. This Court has personal jurisdiction over Slayback for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

8. In addition, this Court has personal jurisdiction over Slayback because, on information and belief, Slayback has engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware.

9. Further, this Court also has personal jurisdiction over Slayback because, among other things, on information and belief: (1) Slayback has filed NDA No. 212209 for the

purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the product described in NDA No. 212209 in the United States, including in Delaware; and (2) Slayback will market, distribute, offer for sale, and/or sell the product described in NDA No. 212209 in the United States, including in Delaware, upon approval of NDA No. 212209, and will derive substantial revenue from the use or consumption of the product described in NDA No. 212209 in the State of Delaware. *See Acorda Therapeutics Inc. v. Hospira Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, if NDA No. 212209 is approved, the product described in NDA No. 212209 would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

10. The Court also has personal jurisdiction over Slayback because it has committed, aided, abetted, induced, contributed to, or participated in the commission of the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Eagle, which is a Delaware corporation.

11. Slayback has previously consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of its abbreviated new drug applications, and it has asserted counterclaims in such cases. *See, e.g.*, *Cephalon, Inc. & Eagle Pharm., Inc. v. Slayback Pharma Ltd. Liability Co.*, No. 17-01154-GMS, D.I. 11 (D. Del. Sept. 29, 2017); *Teva Pharma. Int'l GmbH, Cephalon, Inc. & Eagle Pharma., Inc. v. Slayback Pharma Ltd. Liability Co.*, No. 18-cv-00117, D.I. 9 (D. Del. Feb. 12, 2018); *Eagle Pharm., Inc. v. Slayback Pharma LLC*, No. 18-01459-CFC, D.I. 9 (D. Del. Oct. 10, 2018).

12. For at least the above reasons, it would not be unfair or unreasonable for Slayback to litigate this action in this District, and there is personal jurisdiction over Slayback for purposes of this action.

BACKGROUND

13. BALRAPZO®, which contains bendamustine hydrochloride, is an alkylating drug that is indicated for the treatment of patients with chronic lymphocytic leukemia, as well as for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

14. Eagle is the holder of NDA No. 205580 for BALRAPZO®, which NDA has been approved by the FDA.

15. The ’831 patent, entitled “Formulations of Bendamustine” (Exhibit A hereto), was duly and legally issued on February 23, 2016. Eagle is the owner and assignee of the ’831 patent. The ’831 patent has been listed in connection with BALRAPZO® in the Orange Book.

16. The ’796 patent, entitled “Formulations of Bendamustine” (Exhibit B hereto), was duly and legally issued on February 21, 2017. Eagle is the owner and assignee of the ’796 patent. The ’796 patent has been listed in connection with BALRAPZO® in the Orange Book.

17. The ’797 patent, entitled “Formulations of Bendamustine” (Exhibit C hereto), was duly and legally issued on February 21, 2017. Eagle is the owner and assignee of the ’797 patent. The ’797 patent has been listed in connection with BALRAPZO® in the Orange Book.

18. The '533 patent, entitled "Formulations of Bendamustine" (Exhibit D hereto), was duly and legally issued on July 3, 2018. Eagle is the owner and assignee of the '533 patent. The '533 patent has been listed in connection with BALRAPZO® in the Orange Book.

INFRINGEMENT BY SLAYBACK

19. By a letter dated October 31, 2018 (the "Notice Letter") and received by Eagle thereafter, Slayback notified Eagle pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA") that Slayback had submitted to the FDA NDA No. 212209, seeking approval from the FDA to engage in the commercial manufacture, use, and/or sale of a Bendamustine Hydrochloride Injection, 100 mg/4 mL (25 mg/mL) product (multiple-dose vials) ("Slayback's NDA Product") prior to the expiration of the Patents-in-Suit. Upon information and belief, Slayback's NDA Product relies on data from bioavailability and/or bioequivalence studies contained in the approved labeling for BALRAPZO® and contains the same or equivalent ingredients in the same or equivalent amounts as BALRAPZO® and/or as recited in the claims of the Patents-in-Suit.

20. The purpose of Slayback's submission of NDA No. 212209 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Slayback's NDA Product prior to the expiration of the Patents-in-Suit.

21. In the Notice Letter, Slayback also notified Eagle that, as part of its NDA No. 212209, Slayback had filed a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA ("Paragraph IV Certification") with respect to each of the Patents-in-Suit. Upon information and belief, Slayback submitted a Paragraph IV Certification pursuant to 21 U.S.C. § 355(b)(2)(A)(iv) to the FDA in connection with NDA No. 212209 asserting that the Patents-in-Suit will not be infringed by the manufacture, use, offer for sale, sale, or importation of Slayback's NDA Product, or alternatively, that these patents are invalid or unenforceable.

22. In the Notice Letter, Slayback stated that the active ingredient of Slayback's NDA Product is bendamustine hydrochloride.

23. In the Notice Letter, Slayback stated that the proposed dosage strength of Slayback's NDA Product is 25 mg/mL.

24. Upon information and belief, the proposed labeling for Slayback's NDA Product encourages, recommends, instructs, and/or promotes administration to patients with chronic lymphocytic leukemia.

25. Upon information and belief, the proposed labeling for Slayback's NDA Product recommends, encourages, instructs, and/or promotes administration to patients with indolent B-cell non-Hodgkin lymphoma.

26. This action is being commenced before the expiration of forty-five days from the date of the Eagle's receipt of the Notice Letter.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 9,265,831 UNDER 35 U.S.C. § 271(e)(2)

27. Eagle incorporates each of the preceding paragraphs 1–26 as if fully set forth herein.

28. Slayback's submission of NDA No. 212209 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Slayback's NDA Product prior to the expiration of the '831 patent was an act of infringement of the '831 patent under 35 U.S.C. § 271(e)(2)(A). In the event that Slayback commercially manufactures, imports, uses, offers for sale, or sells Slayback's NDA Product, said actions would constitute infringement of the '831 patent under 35 U.S.C. § 271(a).

29. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's NDA Product would infringe one or more claims of the '831 patent under the doctrine of equivalents.

30. Upon information and belief, Slayback will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's NDA Product immediately and imminently upon FDA approval of NDA No. 212209.

31. The foregoing actions by Slayback constitute and/or will constitute infringement of the '831 patent.

32. Upon information and belief, Slayback has acted with full knowledge of the '831 patent and without a reasonable basis for believing that it would not be liable for infringing the '831 patent.

33. Unless Slayback is enjoined from infringing the '831 patent, Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

COUNT II – INFRINGEMENT OF U.S. PATENT NO. 9,572,796 UNDER 35 U.S.C. § 271(e)(2)

34. Eagle incorporates each of the preceding paragraphs 1–33 as if fully set forth herein.

35. Slayback's submission of NDA No. 212209 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Slayback's NDA Product prior to the expiration of the '796 patent was an act of infringement of the '796 patent under 35 U.S.C. § 271(e)(2)(A). In the event that Slayback commercially manufactures, imports, uses, offers for sale, or sells Slayback's NDA Product or induces or contributes to such conduct, said actions would constitute infringement of the '796 patent under 35 U.S.C. §§ 271 (a), 271(b), and/or 271(c).

36. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's NDA Product would infringe one or more claims of the '796 patent under the doctrine of equivalents.

37. Upon information and belief, Slayback will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's NDA Product immediately and imminently upon FDA approval of NDA No. 212209.

38. Upon information and belief, Slayback will instruct, encourage, promote, and/or recommend the administration of the Slayback NDA Product within the scope of one or more claims of the '796 patent under the doctrine of equivalents. On information and belief, Slayback will market its proposed products to hospitals, clinics, physicians, and other medical care providers and will instruct, encourage, promote, and/or recommend the practice of each of the steps of one or more claims of the '796 patent under the doctrine of equivalents.

39. Upon information and belief, the use of Slayback's NDA Product in accordance with and as directed by Slayback's proposed labeling for that product would infringe one or more claims of the '796 patent under the doctrine of equivalents.

40. Upon information and belief, Slayback plans and intends to, and will, actively induce infringement of the '796 patent when NDA No. 212209 is approved, and plans and intends to, and will, do so after approval.

41. Upon information and belief, Slayback knows that its NDA Product and its proposed labeling are especially made or adapted for use in infringing the '796 patent, and that its NDA Product and its proposed labeling are unsuitable for substantial noninfringing use. Upon information and belief, Slayback plans and intends to, and will, contribute to infringement of the '796 patent after approval of NDA No. 212209.

42. The foregoing actions by Slayback constitute and/or will constitute infringement of the ’796 patent, active inducement of infringement of the ’796 patent, and/or contribution to the infringement by others of the ’796 patent.

43. Upon information and belief, Slayback has acted with full knowledge of the ’796 patent and without a reasonable basis for believing that it would not be liable for infringing the ’796 patent, actively inducing infringement of the ’796 patent, and/or contributing to the infringement by others of the ’796 patent.

44. Unless Slayback is enjoined from infringing the ’796 patent, actively inducing infringement of the ’796 patent, and contributing to the infringement by others of the ’796 patent, Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

COUNT III – INFRINGEMENT OF U.S. PATENT NO. 9,572,797 UNDER 35 U.S.C. § 271(e)(2)

45. Eagle incorporates each of the preceding paragraphs 1–44 as if fully set forth herein.

46. Slayback’s submission of NDA No. 212209 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Slayback’s NDA Product prior to the expiration of the ’797 patent was an act of infringement of the ’797 patent under 35 U.S.C. § 271(e)(2)(A). In the event that Slayback commercially manufactures, imports, uses, offers for sale, or sells Slayback’s NDA Product or induces or contributes to such conduct, said actions would constitute infringement of the ’797 patent under 35 U.S.C. § 271(b) and/or 271(c).

47. The use of Slayback’s NDA Product would infringe one or more claims of the ’797 patent under the doctrine of equivalents.

48. Upon information and belief, Slayback will instruct, encourage, promote, and/or recommend the administration of the Slayback NDA Product within the scope of one or more claims of the '797 patent under the doctrine of equivalents. On information and belief, Slayback will market its proposed products to hospitals, clinics, physicians, and other medical care providers and will instruct, encourage, promote, and/or recommend the practice of each of the steps of one or more claims of the '797 patent under the doctrine of equivalents.

49. Upon information and belief, Slayback will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's NDA Product immediately and imminently upon FDA approval of NDA No. 212209.

50. Upon information and belief, the use of Slayback's NDA Product in accordance with and as directed by Slayback's proposed labeling for that product would infringe one or more claims of the '797 patent under the doctrine of equivalents.

51. Upon information and belief, Slayback plans and intends to, and will, actively induce infringement of the '797 patent when NDA No. 212209 is approved, and plans and intends to, and will, do so after approval.

52. Upon information and belief, Slayback knows that its NDA Product and its proposed labeling are especially made or adapted for use in infringing the '797 patent, and that its NDA Product and its proposed labeling are unsuitable for substantial noninfringing use. Upon information and belief, Slayback plans and intends to, and will, contribute to infringement of the '797 patent after approval of NDA No. 212209.

53. The foregoing actions by Slayback constitute and/or will constitute active inducement of infringement of the '797 patent and/or contribution to the infringement by others of the '797 patent.

54. Upon information and belief, Slayback has acted with full knowledge of the '797 patent and without a reasonable basis for believing that it would not be liable for actively inducing infringement of the '797 patent and/or contributing to the infringement by others of the '797 patent.

55. Unless Slayback is enjoined from actively inducing infringement of the '797 patent and contributing to the infringement by others of the '797 patent, Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

COUNT IV – INFRINGEMENT OF U.S. PATENT NO. 10,010,533 UNDER 35 U.S.C. § 271(e)(2)

56. Eagle incorporates each of the preceding paragraphs 1–55 as if fully set forth herein.

57. Slayback's submission of NDA No. 212209 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Slayback's NDA Product prior to the expiration of the '533 patent was an act of infringement of the '533 patent under 35 U.S.C. § 271(e)(2)(A). In the event that Slayback commercially manufactures, imports, uses, offers for sale, or sells Slayback's NDA Product, said actions would constitute infringement of the '533 patent under 35 U.S.C. § 271 (a).

58. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's NDA Product would infringe one or more claims of the '533 patent under the doctrine of equivalents.

59. Upon information and belief, Slayback will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's NDA Product immediately and imminently upon FDA approval of NDA No. 212209.

60. The foregoing actions by Slayback constitute and/or will constitute infringement of the ’533 patent.

61. Upon information and belief, Slayback has acted with full knowledge of the ’533 patent and without a reasonable basis for believing that it would not be liable for infringing the ’533 patent.

62. Unless Slayback is enjoined from infringing the ’533 patent, Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

COUNT V – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,265,831

63. Eagle incorporates each of the preceding paragraphs 1–62 as if fully set forth herein.

64. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback’s NDA Product would infringe one or more claims of the ’831 patent under the doctrine of equivalents.

65. Upon information and belief, Slayback will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback’s NDA Product immediately and imminently upon FDA approval of NDA No. 212209.

66. Upon information and belief, Slayback has acted with full knowledge of the ’831 patent and without a reasonable basis for believing that it would not be liable for infringing the ’831 patent.

67. Accordingly, there is a real, substantial, and continuing case or controversy between Eagle and Slayback regarding whether Slayback’s manufacture, use, sale, offer for sale, or importation into the United States of Slayback’s NDA Product with its proposed labeling

according to NDA No. 212209 will infringe one or more claims of the '831 patent and whether one or more claims of the '831 patent are valid.

68. Eagle should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Slayback's NDA Product with its proposed labeling would infringe the claims of the '831 patent and that the claims of the '831 patent are valid.

69. Slayback should be enjoined from infringing the '831 patent; otherwise Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

COUNT VI – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,572,796

70. Eagle incorporates each of the preceding paragraphs 1–69 as if fully set forth herein.

71. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's NDA Product would infringe one or more claims of the '796 patent under the doctrine of equivalents.

72. Upon information and belief, Slayback will instruct, encourage, promote, and/or recommend the administration of the Slayback NDA Product within the scope of one or more claims of the '796 patent under the doctrine of equivalents. On information and belief, Slayback will market its proposed products to hospitals, clinics, physicians, and other medical care providers and will instruct, encourage, promote, and/or recommend the practice of each of the steps of one or more claims of the '796 patent under the doctrine of equivalents.

73. Upon information and belief, Slayback will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's NDA Product immediately and imminently upon FDA approval of NDA No. 212209.

74. Upon information and belief, the use of Slayback's NDA Product in accordance with and as directed by Slayback's proposed labeling for that product would infringe one or more claims of the '796 patent under the doctrine of equivalents.

75. Upon information and belief, Slayback plans and intends to, and will, actively induce infringement of the '796 patent when NDA No. 212209 is approved, and plans and intends to, and will, do so after approval.

76. Upon information and belief, Slayback knows that its NDA Product and its proposed labeling are especially made or adapted for use in infringing the '796 patent, and that its NDA Product and its proposed labeling are unsuitable for substantial noninfringing use. Upon information and belief, Slayback plans and intends to, and will, contribute to infringement of the '796 patent after approval of NDA No. 212209.

77. The foregoing actions by Slayback constitute and/or will constitute infringement of the '796 patent, active inducement of infringement of the '796 patent, and/or contribution to the infringement by others of the '796 patent.

78. Upon information and belief, Slayback has acted with full knowledge of the '796 patent and without a reasonable basis for believing that it would not be liable for infringing the '796 patent, actively inducing infringement of the '796 patent, and/or contributing to the infringement by others of the '796 patent.

79. Accordingly, there is a real, substantial, and continuing case or controversy between Eagle and Slayback regarding whether Slayback's manufacture, use, sale, offer for sale, or importation into the United States of Slayback's NDA Product with its proposed labeling according to NDA No. 212209 will infringe one or more claims of the '796 patent and whether one or more claims of the '796 patent are valid and enforceable.

80. Eagle should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Slayback's NDA Product with its proposed labeling would infringe, actively induce the infringement of, and/or contribute to the infringement by others of the '796 patent and that the claims of the '796 patent are valid and enforceable.

81. Slayback should be enjoined from infringing the '796 patent, actively inducing infringement of the '796 patent, and contributing to the infringement by others of the '796 patent; otherwise Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

COUNT VII – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,572,797

82. Eagle incorporates each of the preceding paragraphs 1–81 as if fully set forth herein.

83. Upon information and belief, the use of Slayback's NDA Product would infringe one or more claims of the '797 patent under the doctrine of equivalents.

84. Upon information and belief, Slayback will instruct, encourage, promote, and/or recommend the administration of the Slayback NDA Product within the scope of one or more claims of the '797 patent under the doctrine of equivalents. On information and belief, Slayback will market its proposed products to hospitals, clinics, physicians, and other medical care providers and will instruct, encourage, promote, and/or recommend the practice of each of the steps of one or more claims of the '797 patent under the doctrine of equivalents.

85. Upon information and belief, Slayback will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's NDA Product immediately and imminently upon FDA approval of NDA No. 212209.

86. Upon information and belief, the use of Slayback's NDA Product in accordance with and as directed by Slayback's proposed labeling for that product would infringe one or more claims of the '797 patent under the doctrine of equivalents.

87. Upon information and belief, Slayback plans and intends to, and will, actively induce infringement of the '797 patent when NDA No. 212209 is approved, and plans and intends to, and will, do so after approval.

88. Upon information and belief, Slayback knows that its NDA Product and its proposed labeling are especially made or adapted for use in infringing the '797 patent, and that its NDA Product and its proposed labeling are unsuitable for substantial noninfringing use. Upon information and belief, Slayback plans and intends to, and will, contribute to infringement of the '797 patent after approval of NDA No. 212209.

89. The foregoing actions by Slayback constitute and/or will constitute active inducement of infringement of the '797 patent and/or contribution to the infringement by others of the '797 patent.

90. Upon information and belief, Slayback has acted with full knowledge of the '797 patent and without a reasonable basis for believing that it would not be liable for actively inducing infringement of the '797 patent and/or contributing to the infringement by others of the '797 patent.

91. Accordingly, there is a real, substantial, and continuing case or controversy between Eagle and Slayback regarding whether Slayback's manufacture, use, sale, offer for sale, or importation into the United States of Slayback's NDA Product with its proposed labeling according to NDA No. 212209 will infringe one or more claims of the '797 patent and whether one or more claims of the '797 patent are valid.

92. Eagle should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Slayback's NDA Product with its proposed labeling would actively induce the infringement of and contribute to the infringement by others of the '797 patent and that the claims of the '797 patent are valid.

93. Slayback should be enjoined from actively inducing infringement of the '797 patent and contributing to the infringement by others of the '797 patent; otherwise Eagle will suffer irreparable injury. Eagle has no adequate remedy at law.

COUNT VIII – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,010,533

94. Eagle incorporates each of the preceding paragraphs 1–93 as if fully set forth herein.

95. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's NDA Product would infringe one or more claims of the '533 patent under the doctrine of equivalents.

96. Upon information and belief, Slayback will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Slayback's NDA Product immediately and imminently upon FDA approval of NDA No. 212209.

97. Upon information and belief, Slayback has acted with full knowledge of the '533 patent and without a reasonable basis for believing that it would not be liable for infringing the '533 patent.

98. Accordingly, there is a real, substantial, and continuing case or controversy between Eagle and Slayback regarding whether Slayback's manufacture, use, sale, offer for sale, or importation into the United States of Slayback's NDA Product with its proposed labeling

according to NDA No. 212209 will infringe one or more claims of the '533 patent and whether one or more claims of the '533 patent are valid.

99. Eagle should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Slayback's NDA Product with its proposed labeling would infringe the claims of the '533 patent and that the claims of the '533 patent are valid.

100. Slayback should be enjoined from infringing the '533 patent; otherwise Eagle will suffer irreparable injury. Eagle haves no adequate remedy at law.

WHEREFORE, Eagle requests the following relief:

(a) A judgment that Slayback has infringed, will infringe, and/or will induce and contribute to infringement of the '831 patent, the '796 patent, the '797 patent, and the '533 patent.

(b) A judgment that the Patents-in-Suit are valid and enforceable;

(c) A judgment pursuant to, *inter alia*, 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval for Slayback to make, use, offer for sale, sell, market, distribute, or import Slayback's NDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, be not earlier than the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A preliminary and permanent injunction pursuant to, *inter alia*, 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283 enjoining Slayback, its officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Slayback's NDA Product, or any product the making,

using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

(e) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Slayback's NDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, prior to the expiration date of the Patents-in-Suit, respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the Patents-in-Suit;

(f) An award of Eagle's damages or other monetary relief to compensate Eagle if Slayback engages in the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Slayback's NDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(C);

(g) A declaration that this case against Slayback is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(h) An award of Eagle's costs and expenses in this action; and

(i) Such further and other relief as this Court may deem just and proper.

/s/ Karen E. Keller

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